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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,491	03/19/2004	Mary Cismowski	60388-AB-PCT-US JPW/GJG/J	8086
38724	7590	04/05/2006	EXAMINER	
OSI PHARMACEUTICALS, INC. 41 PINELAWN ROAD MELVILLE, NY 11747			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,491

Applicant(s)

CISMOWSKI ET AL.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005 and 13 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,32-41 and 72-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30,32-34 and 38-41 is/are allowed.
- 6) ☒ Claim(s) 72,74,75,77 and 78 is/are rejected.
- 7) ☒ Claim(s) 35-37,73 and 76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to the Papers filed 15 August 2005 and 13 January 2006 in response to the Non-Final Office Action mailed 21 March 2005. Claims 52-71 were withdrawn from consideration 30-41 and 52-78 were considered in the 21 March Office Action. Claim 30 was amended and claims 31 and 42-71 were canceled in the 13 January Paper. Claims 30, 32-41 and 72-78 are pending and under consideration.

Response to Amendment**Claim Rejections - 35 USC § 112**

Rejection of claims 30, 32, 34-41, 73 and 76 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to claim 30.

Claims 72, 74, 75, 77 and 78 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

As stated in the 21 March Office Action, “[G]iven the functional diversity of AGS proteins which is now known to exist, the skilled artisan would not expect the single disclosed species of ‘a polypeptide capable of inhibiting the activity of the AGS protein’ (*i.e.*, the polypeptide comprising SEQ ID NO: 25) to adequately describe the genus encompassed thereby. That is, the skilled artisan would not have viewed the disclosure of the polypeptide comprising SEQ ID NO: 25, which is capable of inhibiting the activity of the protein comprising SEQ ID NO: 2, as representative of a genus of polypeptides capable of inhibiting the activity of any AGS

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protein. Still further, the skilled artisan would not have viewed the single species as representative of all proteins having the ability to inhibit the activity of a polypeptide comprising SEQ ID NO: 2. Therefore, the skilled artisan would not have viewed the disclosure as providing adequate descriptive support for any polypeptide capable of inhibiting the activity of an AGS protein other than the polypeptide comprising SEQ ID NO: 25...Therefore, only the described ... polypeptide capable of inhibiting the activity of the AGS protein comprising SEQ ID NO: 25 meet the written description provision of 35 U.S.C. §112, first paragraph” (paragraph bridging pages 6-7 and the first full paragraph on page 7). Applicant’s response does not address these grounds for rejection. It is noted that although claims 74 and 77 recite “SEQ ID NO: 25”, the claims state that the nucleic acid “encodes the polypeptide having an amino acid sequence provided in SEQ ID NO: 25”. Given the use of an indefinite article in referring to the sequence, the limitation is most broadly construed as encompassing a nucleic acid encoding any fragment of the sequence provided in SEQ ID NO: 25 (i.e., any two or more consecutive amino acids comprised in SEQ ID NO: 25). Amending the claim to recite, “having the amino acid sequence provided in SEQ ID NO: 25” would overcome this rejection.

Rejection of claims 30, 32, 34-41, 73 and 76 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendments to claim 30.

Claims 72, 74, 75, 77 and 78 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide capable of inhibiting the activity of the

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AGS protein comprising SEQ ID NO: 25, does not reasonably provide enablement for any polypeptide capable of inhibiting the activity of an AGS protein.

As stated in the previous Office Action, “[D]ue to the art recognized unpredictability of the determinants that define a receptor independent AGS protein or a polypeptide capable of inhibiting the activity of any AGS protein and the lack of guidance in the specification or prior art with regard to how to make the molecules required to practice the method, it would require undue experimentation to practice the invention commensurate with the full scope of the claims.” (second paragraph on page 10). Applicant’s response does not address these grounds for rejection. It is again noted claims 74 and 77 are rejected in view of the broad reading of the claim discussed above and amending the claim to recite, “having the amino acid sequence provided in SEQ ID NO: 25” would overcome this rejection.

Claim Rejections - 35 USC § 102

Rejection of claims 30 and 34-41 under 35 U.S.C. 102(a) and (e) as being anticipated by Pausch *et al.* US Patent No. 5,691,188 and rejection of claims 30, 32 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Allen *et al.* US Patent No. 5,573,908 is withdrawn in view of the amendment to claim 30.

New Grounds

Specification

The disclosure is objected to because of the following informalities:

Figures 4 and 5 disclose sequence data without accompanying SEQ ID NO's. The brief description of the drawings should be amended to recite the relevant SEQ ID NO's.

Appropriate correction is required.

Claim Objections

Claims 35-37 are objected to because of the following informalities: Due to an apparent formatting error, the letter "a" now appears where the Greek letter "α" was previously used.

Appropriate correction is required.

Allowable Subject Matter

Claims 30, 32-34 and 38-41 are allowed.

Claims 35-37 are objected to.

Claims 73 and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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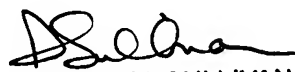
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636


DANIEL M. SULLIVAN
PATENT EXAMINER